

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 6, 2011 has been entered.
2. Claims 2, 3, 11 and 23 were previously canceled. Currently, Claims 1, 4-10, 12-22 and 24-31 are pending.

Response to Arguments

3. Applicant's arguments, see Remarks, filed October 6, 2011, with respect to the rejection of claims 1, 4-5, 13-17, 25-28 and 31 under 35 U.S.C. 102(b) over Bachmann et al, US Patent No. 5,954,729 ("Bachmann") have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new grounds of rejection is made in view of Heyn et al, US Patent No. 5,201,757.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 4-5, 13-17, 25-28 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Heyn et al, US Patent No. 5,201,757.

6. Regarding claims 1 and 13, Heyn discloses a stent deployment device (16, Fig. 1) comprising a support member configured to abut the user's hand (68, Fig. 1); a longitudinally extending outer tubular member (20, 58, 62, Fig. 1) having proximal and distal ends (Fig. 1), the distal end configured to receive the stent such that the stent is slidably disposed in the outer tubular member (stent 18, Fig. 1); an inner tubular member (44, Fig. 1) having distal and proximal ends (Fig. 1); the distal end of the inner tubular member comprising a tip (52, Fig. 1); the inner tubular member is coupled with the support member (Fig. 1) and at least a portion of the inner tubular member is disposed within the outer tubular member such that the inner tubular member is longitudinally and axially displaceable relative to the outer tubular member (Fig. 1).

Heyn also discloses a deployment mechanism coupled with the outer tubular mechanism to allow staged release of the stent (stent release control structure comprising grips 56, 60, Fig. 1), the deployment mechanism comprising first release member (56, Fig. 1) to at least partially move the outer tubular member proximally and longitudinally relative to the inner tubular member (col. 6, lines 24-35), and a second release member (60, Fig. 1) positioned proximal to the first release member and operably connected to the first release member to move the outer tubular member relative to the inner tubular member (Fig. 1, col. 6, lines 24-35); wherein the first and

second release members are configured to be serially retracted to provide staged release of the stent such that retracting the second release member moves the first release member and the outer tubular member proximally and longitudinally relative to the inner tubular member from a first position to a second position to partially deploy the stent, and subsequent retraction of the first release member moves the outer tubular member proximally and longitudinally relative to the inner tubular member from a second position to a third position to fully deploy the stent (Figs. 5a-5d, col. 6, lines 24-35 and col. 7, line 18 to col. 8, line 10).

7. Heyn also discloses a stent (18, Fig. 1) having proximal and distal ends (Fig. 1) where the tip of the inner tubular member engages the proximal end of the stent for advancing the stent toward the distal end of the outer tubular member as the first and second release members move toward the support member (Fig. 1, col. 6, lines 24-35).

8. Regarding claims 4 and 16, Heyn discloses a safety member (72, Fig. 1) for preventing movement of the first release member and the outer tubular member toward the support member beyond a predetermined position of the outer tubular member relative to the inner tubular member (col. 6, lines 20-35).

9. Regarding claims 5 and 17, Heyn discloses that movement of the first release member from the first position to the predetermined position exposes at least a portion of the stent outwardly of the distal end of the outer tubular member (Fig. 1, col. 6, lines 25-35; Figs. 5a-5d, col. 7, line 18 to col. 8, line 10).

10. Regarding claim 14, Heyn discloses that a portion of the stent is exposed outwardly of the distal end of the outer tubular member (Fig. 1, col. 6, lines 24-35).

11. Regarding claim 15, Heyn discloses that the stent is deployed from the distal end of the outer tubular member (Fig. 1, col. 6, lines 24-35).

12. Regarding claim 25, Heyn discloses a method for delivering a stent (col. 6, lines 5-35 and Figs. 5a-5d, col. 7, line 18 to col. 8, line 10) comprising providing a delivery device (16, Fig. 1, col. 6, lines 24-35) including a support member (68, Fig. 1); an outer tubular member (20, 58, 62, Fig. 1) having proximal and distal ends (Fig. 1), the distal end configured to receive the stent (stent 18, Fig. 1) such that the stent is slidably disposed within the outer tubular member (Fig. 1); an inner tubular member (44, Fig. 1) having distal and proximal ends (Fig. 1); the distal end of the inner tubular member comprising a tip (52, Fig. 1); the inner tubular member is coupled with the support member (Fig. 1) and at least a portion of the inner tubular member is disposed within the outer tubular member such that the inner tubular member is longitudinally and axially displaceable relative to the outer tubular member (Fig. 1), and a deployment mechanism coupled with the outer tubular mechanism (56, 60, Fig. 1) to allow staged release of the stent, the deployment mechanism comprising first release member (56, Fig. 1) to at least partially move the outer tubular member relative to the inner tubular member, and a second release member (60, Fig. 1) proximal to the first release member and operably connected to the first release member to move the outer tubular member relative to the inner tubular member (col. 6, lines 24-35), wherein the first and second release members are configured to be serially retracted to provide staged release of the stent; slidably disposing a stent (18) having a proximal end and a distal end (Fig. 1) within a distal portion of the outer tubular member and around a distal

portion of the inner tubular member (Fig. 1), wherein the tip of the inner tubular member engages the proximal end of the stent to advance the stent toward the distal end of the outer tubular member as the outer tubular member moves toward the support member relative to the inner tube (Fig. 1, col. 6, lines 24-35); and positioning the distal portion of the outer tubular member within the anatomical lumen of the patient at a desired location (col. 6, lines 24-35); retracting the second release member in a direction toward the support member to thereby retract the first release member and the outer tubular member relative to the inner tubular member from a first position to a second position to partially deploy the distal end of the stent (col. 6, lines 24-35, Fig. 1); and retracting the first release member in a direction toward the support member and toward the second release member to thereby retract the outer tubular member relative to the inner tubular member from a second position to a third position to completely deploy the stent in the anatomical lumen of the patient (col. 6, lines 24-35, Fig. 1).

13. Regarding claim 26, Heyn discloses that a portion of the stent is exposed outwardly of the distal end of the outer tubular member (Fig. 1, col. 6, lines 24-35).

14. Regarding claim 27, Heyn discloses that the stent is deployed from the distal end of the outer tubular member (Fig. 1, col. 6, lines 24-35).

15. Regarding claim 28, Heyn discloses preventing movement of the first release member and the outer tubular member toward the support member beyond a predetermined position of the outer tubular member relative to the inner tubular member (prevent movement of the release members beyond a predetermined position, Fig. 1, col. 6, lines 24-35).

16. Regarding claim 31, Heyn discloses that the deployment mechanism can be operable without initially disengaging a safety mechanism (col. 6, lines 24-35).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. Claims 6 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heyn.

19. Regarding claims 6 and 18, Heyn discloses the claimed invention except for the amount of the stent exposed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to expose about 5 to about 95 percent of the stent since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

20. Claims 8, 20, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heyn in view of Bui et al, US Patent No. 6,413,269 B1.

21. Regarding claims 8, 20 and 29, Heyn discloses that an endoscope or telescope can be used to check the locating of the delivery device, but does not explicitly disclose details of the endoscope. However, Bui et al teaches an elongated viewing device

having a proximal and distal end (“endoscope” col. 4, lines 10-25), slidably disposed in the outer tubular member (col. 4, lines 10-25). While Bui et al does not specifically disclose the endoscope extending proximally of the proximal end of the outer tubular member, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the endoscope in a manner such that the proximal end of the viewing device extends outwardly of the proximal end of the outer tubular member in order to allow a user to engage the device with his or her eye, whereas if the proximal end of the endoscope did not extend proximal to the proximal end of the outer tubular member, the endoscope would require additional components for actual use.

22. Claims 7, 9, 10, 12, 19, 21, 22, 24, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heyn in view of Derus et al, US Publication No. 2002/0183827 (hereinafter referred to as Derus).

23. Regarding claims 7 and 19, Heyn lacks the teaching that the safety member comprises a removable tab disposed between the support member and the outer tubular member. However, Derus teaches a safety member comprising a removable tab (56, Figure 6 shows the tab disposed between the distal end of the outer tubular member and the stabilizing member). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the safety member of Heyn with the removable tab as taught by Derus in order to maintain the outer tube in position until deployment of the stent (Derus, paragraph 0043).

24. Regarding claims 9, 21 and 30, Heyn discloses the claimed invention except for means for releasably securing the viewing device. However, Derus teaches means for releasably securing the viewing device (106). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the support of Heyn with the securing means as taught by Derus in order to releasably secure an endoscope in order to view the stent and determine proper placement of the stent (Derus, paragraph 0053).

25. Regarding claims 10 and 22, Heyn discloses the claimed invention except for the viewing device securing means is associated with the stabilizing member. However, Derus teaches that the securing means is associated with the stabilizing member (see Figure 5b). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the support of Heyn with the securing means as taught by Derus in order to releasably secure an endoscope in order to view the stent and determine proper placement of the stent (Derus, paragraph 0053).

26. Regarding claims 12 and 24, Heyn and Derus disclose the claimed invention except for threadingly attaching the clamp. It would have been an obvious matter of design choice to use a threaded clamp, since applicant has not disclosed that threading solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with any sort of clamp, such as a press-fit clamp or a snap-fit clamp.

Conclusion

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Katrina Stransky whose telephone number is (571) 270-3843. The examiner can normally be reached on Monday through Friday, 8:30 am to 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Gary Jackson, at (571) 272-4697.*** The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to
TC3700_Workgroup_D_Inquiries@uspto.gov.

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Examiner, Art Unit 3734
January 12, 2012

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